

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: A12946B**

**Product name: REVUS JARDIN**

**Active Substance:**  
**mandipropamid, 250 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation and label extensions)**  
**non-professional**  
**field uses**

**Applicant: SYNGENTA France SAS**

**Date: 2018-01-16**

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## PART A – Risk Management

The company SYNGENTA France SAS has requested marketing authorisation in France for the product REVUS JARDIN<sup>1</sup> (formulation code: A12946B), containing 250 g/L mandipropamid for use as a fungicide for home garden (non-professional) uses only.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to REVUS JARDIN (A12946B) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of REVUS JARDIN (A12946B) have been made using endpoints agreed in the EU peer review of mandipropamid.

This document describes the specific conditions of use and labelling required for France for the registration of REVUS JARDIN (A12946B).

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of Access.

## 1 DETAILS OF THE APPLICATION

### 1.1 Application background

The present registration report concerns the evaluation of SYNGENTA France SAS's application to market REVUS JARDIN (A12946B) in France as a fungicide (product uses described under point 2.3). France acted as zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation and the major label extensions of this product in France and in other MSs of the Southern zone. France acted as zRMS for the "open air" uses only. Austria acted as inter-zonal RMS (izRMS) in other MSs of the European Union for the uses under protection.

### 1.2 Active substance approval

#### Mandipropamid

Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 approving the active substance mandipropamid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Specific provisions of Regulation (EU) No 188/2013 were as follows:

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandipropamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis.

The applicant shall submit to the Commission, the Member States and the Authority that information by

<sup>1</sup> A separate Registration Report covers the professional product, REVUS, which is an identical formulation.

31 July 2015.

An EFSA conclusion is available (EFSA Journal 2012;10(11):2935).

A Review Report is available (SANCO/ 12991/2012 rev 4 1 February 2013).

### 1.3 Regulatory approach

The present applications were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>2</sup> in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)<sup>3</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The present applications (2014-0328 and 2014-0330) embody two different evaluations:

- (1) Use of REVUS JARDIN (A12946B) as a fungicide in open fields was evaluated by France in the context of the zonal procedure for all Member States of the Southern Zone, taking into account the worst-case uses (“risk envelope approach”)<sup>4</sup> – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.
- (2) A request for work-sharing based on the evaluation of the product REVUS JARDIN (A12946B) in Austria (interzonal evaluation), for use as a fungicide treatment for crops grown under protection.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017<sup>5</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009<sup>6</sup>, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011<sup>7</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>8</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision

<sup>2</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>3</sup> SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

<sup>4</sup> SANCO document “risk envelope approach”, European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”; SANCO/11244/2011 rev. 5

<sup>5</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>

<sup>6</sup> REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

<sup>7</sup> COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

<sup>8</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>9</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of REVUS JARDIN (A12946B), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

## 1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

# 2 DETAILS OF THE AUTHORISATION

## 2.1 Product identity

<b>Product name (code)</b>	REVUS JARDIN (A12946B)
<b>Authorisation number</b>	2171187
<b>Function</b>	Fungicide
<b>Applicant</b>	SYNGENTA France SAS
<b>Composition</b>	250 g/L mandipropamid
<b>Formulation type (code)</b>	Suspension concentrate (SC)
<b>Packaging</b>	Bottles glass (30 mL, 50 mL, 250mL, 500 mL) with a dosing system Bottles HDPE (30 mL, 50 mL, 250mL, 500 mL) with a dosing system Bottles PET (30 mL, 50 mL, 250mL, 500 mL) with a dosing system

## 2.2 Classification and labelling


### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

### 2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

<b>Physical hazards</b>	-
<b>Health hazards</b>	-
<b>Environmental hazards</b>	Aquatic Chronic 2

<sup>9</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<b>Hazard pictograms</b>		
<b>Signal word</b>	-	
<b>Hazard statements</b>	H411	Toxic to aquatic life with long-lasting effects.
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

*See Part C for justifications of the classification and labelling proposals.*

### 2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

The authorisation of the preparation is linked for home garden (non-professional) uses only to the following conditions:

Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.

Do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).

### 2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment <sup>10</sup> : refer to the Decision in Appendix 1 for the details		
Re-entry period <sup>11</sup> : (only after complete drying of area)		
Pre-harvest interval <sup>12</sup> :	Potato	21 days
	Tomato, eggplant, melon and cucurbits with inedible peel	3 days
	Lettuce (and similar) and fresh herbs	7 days
Other mitigation measures:		
The label must include the following recommendations:		
- The label must carry the phrases: “Authorised for home garden use”		
The label must reflect the conditions of authorisation.		

<sup>10</sup> If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

<sup>11</sup> The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

<sup>12</sup> According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. , date: 2018-01-16

PPP (product name/code) **REVUS JARDIN (A12946B)**  
active substance 1 **mandipropamid**  
Applicant: **SYNGENTA France SAS**  
Zone(s): **southern EU (fiel uses)**  
Verified by MS: **yes**  
Field of use: **fungicide**

Formulation type: **suspension concentrate (SC)**  
Conc. of a.s. 1: **250 g/L**  
professional use ☐  
non-professional use ☒

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use No.	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/ synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. Number a) per use b) per crop/ season	Minimum interval between application s (days)	mL product/10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	g mandipropamid / ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	France	Potato	F	<i>Phytophthora infestans</i>	foliar spray	BBCH 31-91	a) 6 b) 6	7	a) 0.6 b) 3.6	a) 150 b) 900	100-600	21	Not acceptable (resistance risk)
	France	Potato	F	<i>Phytophthora infestans</i>	foliar spray	BBCH 31-91	<b>a) 4</b> <b>b) 4</b>	7	a) 0.6 mL/10 m <sup>2</sup> b) 2.4 mL/10 m <sup>2</sup>	a) 150 b) 600	100-600	21	Acceptable (resistance risk : limitation to 4 applications)
	France	Lettuce, rucola, rocket, scarole, lambs, chicory, and other salads	F	<i>Bremia lactucae</i>	foliar spray	BBCH 11-49	a) 2 b) 2	7	a) 0.6 mL/10 m <sup>2</sup> b) 1.2 mL/10 m <sup>2</sup>	a) 150 b) 300	100-1000	7	Acceptable

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use No.	Member state(s)	Crop and/or situation (crop destination/ purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/ synergist per ha
					Method/ Kind	Timing/ Growth stage of crop & season	Max. Number a) per use b) per crop/ season	Minimum interval between application s (days)	mL product/10 m <sup>2</sup> a) max. rate per appl. b) max. total rate per crop/season	g mandipropamid / ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	France	Fresh herbs	F	<i>Plasmopara crustosa</i> , <i>Peronospora spp...</i> “Oomycetes”,	foliar spray	BBCH 11-49	a) 2 b) 2	7	a) 0.6 mL/10 m <sup>2</sup> b) 1.2 mL/10 m <sup>2</sup>	a) 150 b) 300	100-1000	7	Acceptable
	France	Tomato, eggplants	F	<i>Phytophthora infestans</i>	foliar spray	BBCH 21-89	a) 4 b) 4	7	a) 0.6 mL/10 m <sup>2</sup> b) 2.4 mL/10 m <sup>2</sup>	a) 150 b) 600	300-1500	3	Acceptable
	France	Melon, watermelon, pumpkin and other cucurbits with inedible peel	F	<i>Pseudoperonospora cubensis</i>	foliar spray	BBCH 11-89	a) 4 b) 4	7	a) 0.6 mL/10 m <sup>2</sup> b) 2.4 mL/10 m <sup>2</sup>	a) 150 b) 600	600-1200	3	Acceptable

**Remarks columns:**

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
- 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
- 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
- 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- 8 The maximum number of application possible under practical conditions of use must be provided.
- 9 Minimum interval (in days) between applications of the same product
- 10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
- 13 PHI - minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions



### 3 RISK MANAGEMENT

#### 3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

##### 3.1.1 Physical and chemical properties

The formulation REVUS JARDIN (A12946B) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements, including the critical GAP, and the results are deemed acceptable. The appearance of the product is that of a light beige liquid with no particular odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature of 480 °C. In aqueous dispersion (1 %), it has a pH of 6.9 at 25 °C. There is no effect of low and high temperatures on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PET and HDPE. As the stability was performed on HDPE packaging, the glass packaging can be considered acceptable. Its technical characteristics are acceptable for a suspension concentrate.

The formulation is not classified for the physico-chemical aspect.

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance and its relevant impurity (SYN 545038<sup>13</sup>) in the formulation REVUS JARDIN (A12946B) are available and validated.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of mandipropamid in plants (tomato, lettuce, fresh herbs, melon, potatoes), foodstuffs of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids.

##### 3.1.3 Mammalian Toxicology

###### 3.1.3.1 Acute Toxicity

The Acceptable Operator Exposure Level for the active substance fixed at the time of its approval is 0.17 mg/kg bw/d. It was determined on the basis of the no observed adverse effect level (NOAEL) in a 90-day rat oral toxicity study, corrected for 70 % oral absorption, and a 100-fold safety factor.

###### 3.1.3.2 Operator Exposure

Dermal absorption values used for the calculation were 0.2 % for the undiluted product and 0.8 % for the diluted product, based on *in vivo* tests in the rat and *in vitro* studies on rat/human epidermis undertaken with the product.

Estimated operator (i.e., user – non-professional) exposure was calculated according to the French UPJ model<sup>14</sup>:

Crop	Method of application	Maximum rate of use (amount of active substance/ha)	Model
Potato	Pre-pressurised sprayer	0.6 L (150 g a.s./ha)	UPJ 2005

Estimated operator exposure, expressed as a percentage of the AOEL, is as follows:

<sup>13</sup> SYN 545038 : *N*-(2-[4-(2-chloro-allyloxy)-3-methoxy-phenyl]-ethyl)-2-(4-chloro-phenyl)-2-prop-2-ynyloxy-acetamide

<sup>14</sup> Studies submitted by the Union des entreprises pour la Protection des Jardins et des espaces verts (UPJ, the French trade association for garden/amenity pesticide manufacturers) in 2005, to allow assessment of the exposure of home gardeners

Method of application	Personal protective equipment or working coverall	% AOEL mandipropamid
Pre-pressurised sprayer	None	1.7

Hence the risk is considered acceptable for the potato use in home gardens without personal protective equipment. The use on potato covers the other crops (risk envelope).

### 3.1.3.3 Bystander Exposure

In the context of use by non-professionals, it is considered that the evaluation for bystander is covered by that of the operator.

### 3.1.3.4 Worker Exposure

In the case of home garden uses, the worker is often the person applying the product.

It is essential to allow the treated zone or plants to dry fully before touching them.

## 3.1.4 Residues and Consumer Exposure

### 3.1.4.1 Residues

Based on the data presented, the levels of residues measured and the distribution of results indicate that, for the proposed cGAP, the uses will not lead to the extant MRLs being exceeded.

### 3.1.4.2 Consumer exposure

It was deemed unnecessary to set an ARfD for mandipropamid. The levels of estimated chronic exposure are less than the ADI of the active substance and, for potato use, than the TTC<sup>15</sup> for metabolite SYN500003 with pre-harvest interval indicated above.

## 3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of mandipropamid and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU review or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for mandipropamid and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for mandipropamid and its metabolite do not occur at levels exceeding those mentioned in Regulation EC 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

There are no specific implications for labelling resulting from environmental assessment.

<sup>15</sup> Threshold of Toxicological Concern (Austria, 2012. Final Addendum to Draft Assessment Report on mandipropamid, compiled by EFSA, July 2012)

### 3.1.6 Ecotoxicology

The risk assessment of the formulation A12946B (REVUS JARDIN) was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms, micro-organisms and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable only if the product is not applied within 5 meters of a water source;

### 3.1.7 Efficacy

This is a request an authorisation of REVUS JARDIN (A12946B) for use on potato against late blight, plus use extension against late blight on tomato and downy mildew on lettuce, melon, and fresh herbs.

The product dossier and data comply with the Uniform Principles.

Considering the data submitted:

- ✓ The efficacy of REVUS JARDIN (A12946B) is considered satisfactory.
- ✓ The selectivity of REVUS JARDIN (A12946B) is considered satisfactory.
- ✓ The risk of negative impact (on yield, quality, propagation, succeeding and adjacent crops) is considered negligible.
- ✓ For potato, resistance risk is considered as moderate. A limitation to four applications (maximum).
- ✓ Resistance risk is considered as moderate for the other crops (label extension).

### Requested use for REVUS JARDIN (A12946B)

USE	REVUS JARDIN (A12946B) DOSE RATE (L/ha)	Number of applications	zRMS efficacy conclusion
15653201 Potato * Late blight	0.6	<del>6</del> 4	6 applications requested; limitation to 4 applications maximum per year is required on potato.
16603207 Lettuce – downy mildew	0.6	2	-
16953201 Tomato – downy mildew	0.6	4	
16753208 Melon – downy mildew	0.6	4	
16753208 Fresh herbs – downy mildew	0.6	2	

### **3.2 Conclusions arising from French assessment**

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

The composition of the formulation and its classification are compatible with French legislative requirements and allow the product label to include the phrase: “Use authorised in home gardens”

### **3.3 Substances of concern for national monitoring**

-

### **3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation**

#### **3.4.1 Post-authorisation monitoring**

-

#### **3.4.2 Post-authorisation data requirements**

-

#### **3.4.3 Label amendments**

-

## Appendix 1 – Copy of the French Decision



### Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

*Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,*

*Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,*

*Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique*  
**REVUS JARDIN**

de la société SYNGENTA FRANCE SAS  
enregistrées sous les n°2014-0328 et n°2014-0330

*Vu les conclusions de l'évaluation de l'Anses du 15 novembre 2017,*

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

#### **Avertissement :**

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



Informations générales sur le produit		
Nom du produit	REVUS JARDIN	
Type de produit	Deuxième gamme	
Titulaire	SYNGENTA FRANCE SAS 12 Chemin de l'Hobit 31790 Saint Sauveur FRANCE	
Formulation	Suspension concentrée (SC)	
Contenant	250 g/L - mandipropamid	
Produit de référence	Nom commercial	REVUS
	N° AMM	2080098
Numéro d'intrant	2070518	
Numéro d'AMM	2171187	
Fonction	Fongicide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 juillet 2024.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le

1 6 JAN. 2018

**Françoise WEBER**  
Directrice générale déléguée  
en charge du pôle produits réglementés  
Agence nationale de sécurité sanitaire de  
l'alimentation, de l'environnement et du travail (ANSES)

REVUS JARDIN  
AMM n°2171187

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## ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité avec dosette	30 mL ; 50 mL ; 250 mL ; 500 mL
Bouteilles en polyéthylène téréphtalate avec dosette	30 mL ; 50 mL ; 250 mL ; 500 mL
Bouteilles en verre avec dosette	30 mL ; 50 mL ; 250 mL ; 500 mL

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Dangers pour le milieu aquatique - Danger chronique, catégorie 2	H411 : Toxique pour les organismes aquatiques, entraîne des effets à long terme
EUH208 : Contient de la 1,2-benzisothiazol-3(2H)-one. Peut produire une réaction allergique.	
Pour les phrases P se référer à la réglementation en vigueur.	
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	





### Liste des usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
00002022 Arbres et arbustes*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	-	Non applicable	5	-	-	-
	Uniquement sur arbustes. Intervalle minimum entre les applications : 7 jours.							
17403204 Cultures florales et plantes vertes*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	-	Non applicable	5	-	-	-
	Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.							
19153202 Fines Herbes*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	2/an	entre les stades BBCH 11 et BBCH 49	7	5	-	-	-
	Intervalle minimum entre les applications : 7 jours.							
	0,6 mL/10 m²	1/an	entre les stades BBCH 11 et BBCH 49	7	-	-	-	-
16603207 Laitue*Trt Part.Aer.*Mildiou(s)	Uniquement autorisé sous abri.							
	0,6 mL/10 m²	1/an	entre les stades BBCH 11 et BBCH 49	7	-	-	-	-
	Uniquement autorisé sous abri.							
	0,6 mL/10 m²	2/an	entre les stades BBCH 11 et BBCH 49	7	5	-	-	-
	Intervalle minimum entre les applications : 7 jours.							

REVUS JARDIN  
AMM n°2171187

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### Liste des usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
<b>16753208</b> Melon*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	entre les stades BBCH 11 et BBCH 89	3	5	-	-
	Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.						
<b>15653201</b> Pomme de terre*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	entre les stades BBCH 31 et BBCH 91	21	5	-	-
	Intervalle minimum entre les applications : 7 jours. Diminution de 6 à 4 du nombre d'applications en raison d'un risque de résistance au mandipropamid.						
<b>17303205</b> Rosier*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	-	Non applicable	5	-	-
	Également autorisé sous abri. Intervalle minimum entre les applications : 7 jours.						
<b>16953201</b> Tomate*Trt Part.Aer.*Mildiou(s)	0,6 mL/10 m²	4/an	entre les stades BBCH 21 et BBCH 89	3	5	-	-
	Intervalle minimum entre les applications : 7 jours.						
	0,6 mL/10 m²	4/an	entre les stades BBCH 11 et BBCH 89	3	-	-	-
Uniquement sous abri. Intervalle minimum entre les applications : 7 jours.							

REVUS JARDIN  
AMM n°2171187

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### Conditions d'emploi du produit

#### **Délai de rentrée :**

- Attendre le séchage complet de la zone traitée.

#### **Respect des limites maximales de résidus (LMR)**

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

#### **Protection de l'environnement (milieux, faune et flore)**

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidons non utilisés et les eaux de lavage du pulvérisateur.

- Ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé ...).

Appendix 2 – Copy of the draft product label as proposed by the applicant



**REVUS® JARDIN**  
H411 Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.  
• P101 En cas de consultation d'un médecin, garder à disposition le récipient ou l'étiquette • P102 Tenir hors de portée des enfants • P270 Ne pas manger, boire ou fumer en manipulant ce produit • P273 Éviter le rejet dans l'environnement • P301 + P310 EN CAS D'INGESTION : appeler immédiatement un CENTRE ANTIPOISON ou un médecin • P391 Recueillir le produit répandu • P501 Éliminer le contenu / récipient dans une déchèterie ou par un organisme agréé  
• EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement • SP1 Ne pas polluer l'eau avec le produit ou son emballage • SPa3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.  
Distribué par : COMPO France SAS - Division Grand public  
Z.I. - 25220 ROCHE LEZ BEAUPRE - Tél. : 03 81 40 25 25



## ALGOFLASH

**Anti Mildiou**  
**Pommes de terre**  
REVUS® JARDIN

Revus® Jardin est un fongicide spécialement conçu pour la lutte contre le mildiou de la pomme de terre (*Phytophthora infestans*).

Il protège à la fois les feuilles, les jeunes pousses en période de croissance et les tubercules, pour un rendement optimisé.  
Il s'utilise aussi contre le mildiou des laitues, tomates, melons et fines herbes.

**Lire les instructions ci-jointes avant l'emploi.**

® Marque enregistrée d'une société du groupe Syngenta  
\* Substance active brevetée par une société du groupe Syngenta

Nom homologué : REVUS® JARDIN - N° d'AMM : 2000098  
Emploi autorisé dans les jardins.  
Défendeur de l'AMM : SYNGENTA France SAS venant aux droits de Syngenta Agro SAS : 1 avenue des Prés - CS 10 537 - 78206 GIVANCOURT  
siège social : 12 Chemin de l'habitat, 31 790 Saint Saut.  
Composition : 250 g/L (23,4% (m/m)) de Mandipropamide\*.  
Formulation : suspension concentrée - fongicide.

**USAGES :** Traitement des parties aériennes - Pomme de terre, laitue, tomate, melon et fines herbes - Mildiou : 0,6 mL/10 m<sup>2</sup>  
Zone non traitée (ZNT) : 5 mètres.

Délais avant récolte et nombre maximum d'applications : voir tableau au dos de l'étui.  
Port des gants nitrile lors des phases de préparation et d'utilisation recommandée.  
Délai de rentrée : attendre le séchage complet de la zone traitée.  
Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseau, étang, mare, puits... en particulier si le terrain est en pente.  
Conserver uniquement dans l'emballage d'origine, à l'écart des aliments et bois sans y compris ceux pour animaux. Ne pas réutiliser l'emballage vide.

**Appel en cas d'urgence : 15 ou centre anti-poison**



**Volume Net : 20 mL**

**44520FE3**

### **Appendix 3 – Letter(s) of Access**

Not applicable.